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TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			FAULK, DEVONA E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/721,462	Applicant(s) SHENNIB, ADNAN	
	Examiner Devona E. Faulk	Art Unit 2644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments, filed, 9/10/2204 with respect to the rejection(s) of claim(s) 1,10,12,13,22 and 24 under 102 (b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Haertl.

2. Applicant's arguments, filed 9/10/2004, with respect to the rejection(s) of claim(s) 2,4,5,7,14,16,17,19 and 25 under 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Haertl.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1,3,4-6,10,13,15,16-18,22 and 25** are rejected under 35 U.S.C. 102(b) as being anticipated by Haertl (U.S. Patent 4,987,597).

Regarding claim 1, Haertl discloses an intracanal shield (12, Figure 1; column 3, lines 7-34) for positioning entirely in the ear canal and capping the cavity of said ear canal, comprising a conforming perimeter adapted to fit in a retaining manner along the cross sectional wall of the ear canal cavity; a central porous member having pores sized for allowing air to pass through

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said porous member while preventing passage of fluids and solids therethrough, said intracanal shield (Figures 4-11; column 3, lines 20-33; column 4, lines 1-25), when fitted in said retaining manner in the ear canal cavity, being positioned laterally with respect to a miniature hearing device medially positioned in close proximity to the eardrum, whereby to protect said hearing device against penetration of fluids and debris through said porous member while allowing air-borne sounds to reach said hearing device (column 3, lines 10-20).

All elements of **claim 3** are comprehended by claim 1.

All elements of **claims 4-6** are comprehended by claim 1.

**Claim 10** claims the intracanal shield of claim 1, wherein said pores are sized in the range of 1 to 10 microns. Regarding claim 10, Haertl discloses a micro-porous membrane (column 3, line 10-12), which reads on the claim language.

Regarding **claim 13**, Haertl discloses a hearing system (Figure 1) fabricated and adapted to be positioned entirely in the ear canal for extended wear (column 3), comprising a hearing device (Figure 1) assembled and dimensioned to be medially positioned in the ear canal and an intracanal shield (12, Figure 1; column 3, lines 20-33) shaped and dimensioned to be laterally positioned with respect to said hearing device, so that said intracanal shield caps the cavity of said ear canal, said intracanal shield comprising a conforming perimeter for fitting in a retaining manner along the cross sectional wall (column 4, lines 26-30) of the ear canal and a central porous member for air ventilation with respect to said hearing device, and having pores sized to prevent penetration of fluids and solids therethrough (column 3, lines 10-20).

All elements of **claim 15** are comprehended by claim 13.

All elements of **claims 16-18** are comprehended by claim 13.

**Claim 22** claims the hearing system of claim 13, wherein said pores are sized in the range of 1 to 10 microns. Haertl discloses of a micro-porous membrane (column 3, line 10-12), which reads on the claim language.

Regarding **claim 25** Haertl discloses an acoustically permeative cap shaped and dimensioned to be positioned entirely in the ear canal for extended wear therein to protect a medially positioned hearing device within the ear canal against infiltration of fluids and debris, said cap being hydrophobic and porous with pores sized to prevent fluids and solids from penetration, but allow air-borne sound passage, therethrough into the ear canal toward said hearing device (Figure 1; column 3, lines 10-33).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claim 2,7 ,14,16,17 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Flagler (U.S. Patent 6,134,333).

**Claim 2** claims the intracanal shield of claim 1, wherein said intracanal shield is separate from said canal hearing device for independent insertion and removal while said hearing device is positioned in-situ. As stated above apropos of claim 1, Haertl meets all elements of that claim. Therefore Haertl meets all elements of claim 2 with the exception of the intracanal shield being separate from said canal hearing device for independent insertion and removal while said hearing

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device is positioned in-situ. Regarding claim 2, Flagler discloses a cerumen barrier (10) including a sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14), the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes too great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Flagler's concept of independent insertion as claimed for the benefit of having a shield that is more easily replaced.

**Claim 7** claims the intracanal shield of claim 1, wherein said intracanal shield is composed of disposable material for cost-effective single use of said shield. As stated above apropos of claim 1, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 7 with the exception of the claimed matter. Regarding claim 7, Flagler discloses a cerumen barrier (10) including a sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14), the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes too great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Flagler's concept of a disposable shield for the benefit of having a cerumen barrier that is more easily replaced.

**Claim 14** claims the hearing system of claim 13, wherein said intracanal shield is separate from said hearing device for independent insertion into and removal from the ear while said hearing device is positioned in-situ. As stated above apropos of claim 13, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 14 with the exception of the claimed matter. Regarding claim 14, Flagler discloses a cerumen barrier (10) including a

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sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14) , the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes to great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Oliveria's wax guard so that the barrier was capable of being inserted as claimed for the benefit of having a cerumen barrier that is more easily replaced.

**Claim 19** claims the hearing system of claim 13, wherein each of said hearing device and said hearing device and said intracanal shield is disposable. As stated above apropos of claim 13, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 19 with the exception of the claimed matter. Regarding claim 19, Flagler discloses a cerumen barrier (10) including a sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14) , the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes to great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Flagler's concept of a disposable shield for the benefit of having a cerumen barrier that is more easily replaced.

7. **Claims 12 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Oliveira (U.S. Patent 5,401,920).

**Claims 12 and 24** claim the intracanal shield of claim 1 and the hearing system of claim 13 respectively, wherein said intracanal shield has an oval cross-sectional shape adapted to fit comfortably in a cross section of the ear canal. Oliveira discloses the concept of an intracanal shield having an oval cross-sectional shape (Figure 1). Thus it would have been obvious to one

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of ordinary skill in the art at the time of the invention to use Oliveira's concept of an intracanal shield having an oval cross-sectional shape in order to better conform to

8. **Claims 8,9,11,20,21,23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Brown et al. (U.S Patent 6,129,174).

**Claim 8** claims the intracanal shield of claim 1, wherein said shield is at least partially composed of polyurethane foam. As stated above apropos of claim 1, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 8 with the exception of the claimed matter. Regarding claim 8, Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of polyurethane foam for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

**Claim 9** claims the intracanal shield of claim 1, wherein said shield is at least partially composed of silicone material. As stated above apropos of claim 1, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 9 with the exception of the claimed matter. Regarding claim 9, Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of silicone for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.



**Claim 11** claims the intracanal shield of claim 1, wherein said intracanal shield is shaped and dimensioned to be positioned deep in the ear canal past the hair and cerumen production area therein. As stated above apropos of claim 1, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 11 with the exception of the claimed matter. Regarding claim 11, Brown discloses a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), adapted for use with an intracanal receiver module can be deeply inserted into the ear canal of the user while making minimal contact with the walls of the ear canal (See Abstract). Therefore, the concept of having a intracanal device that can be deeply inserted in the ear canal was well known at the time of filing. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Brown's concept of deeply inserting an intracanal shield so that it could be inserted deeply into the ear for the benefit of enabling a deeper insertion of the hearing aid.

**Claim 20** claims the hearing system of claim 13, wherein said intracanal shield is wherein said shield is at least partially composed of polyurethane foam. As stated above apropos of claim 13, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 20 with the exception of the claimed matter. Regarding claim 20, Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of polyurethane foam for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

**Claim 21** claims the hearing system of claim 13, wherein said shield is at least partially composed of silicone material. As stated above apropos of claim 13, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 21 with the exception of the claimed matter. Regarding **claim 21**, Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of silicone for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

**Claim 23** claims the hearing system of claim 13, wherein said shield is fabricated and dimensioned to be positioned deep in the ear canal past the hair and cerumen production therein. As stated above apropos of claim 13, Haertl meets all elements of that claim. Therefore, Haertl meets all elements of claim 23 with the exception of the claimed matter. Regarding **claim 23**, Brown discloses a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), adapted for use with an intracanal receiver module can be deeply inserted into the ear canal of the user while making minimal contact with the walls of the ear canal (See Abstract). Therefore, the concept of having a intracanal device that can be deeply inserted in the ear canal was well known at the time of filing. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Brown's concept of deeply inserting an intracanal device for the benefit of enabling a deeper insertion of the hearing aid.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to intracanal caps in general:

U.S. Patent No. 6,164,409 to Berger

U.S. Patent No. 6,000,492 to Puthuff et al.

U.S. Patent No. 6,105,713 to Brimhall et al.

U.S. Patent No. 5,327,500 to Campbell

U.S. Patent No. 4,553,627 to Gastmeier et al.

U.S. Patent No. 4,870,689 to Weiss

U.S. Patent No. 4,706,689 to Topholm

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devona E. Faulk whose telephone number is 703-305-4359. The examiner can normally be reached on 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Forester W. Isen can be reached on 703-305-4386. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER